

K973101 PROSTATE SPECIFIC ANTIGEN METHODSep 18, 1997
30 days to decisionK973101 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k973101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Aug 19, 1997
Decision date	Sep 18, 1997
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Chemistry Systems, Inc.
Location	Newark, DE, US
Contact	REBECCA S AYASH
510(k) history	13 submissions · 13 cleared · 1996-1997

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